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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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GE MEDICAL SYSTEM
C/O FOLEY & LARDNER LLP
777 EAST WISCONSIN AVENUE
MILWAUKEE, WI 53202-5306

EXAMINER

KHOLDEBARIN, IMAN KENNETH

ART UNIT	PAPER NUMBER
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3709

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,424

Applicant(s)

LI ET AL.

Examiner

I Kenneth Kholdebarin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12-13-2003, 4-26-2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

1. The replacement drawings were received on 05/14/2006. These drawings are acceptable.

Claim Objections

2. Claim 1, 4, 5, 6, 7, 12 and 16 objected to because of the following informalities:

Claim 1, line 4: "an image of the heart using the feature" should be -- an image of the
feature of the heart--.

Claim 4, line 2: "an interior surface of the heart" should be -- an interior of the heart--.

Claim 5, line 2: "resonance and/or ultrasound" should be -- resonance or ultrasound--.

Claim 6, line 2: "and/or scar tissue" should be -- or scar tissue--.

Claim 7, line 1: "at least a three dimensional" should be -- at least three-dimensional--.

Claim 12, line 5: "memory configured" should be -- a memory configured--.

Claim 16, line 2: "magnetic resonance, and/or ultrasound" should be -- magnetic
resonance, or ultrasound --.

Claim 21, line 2: "magnetic resonance, and/or ultrasound" should be -- magnetic
resonance or ultrasound--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 17 and 21 rejected under 35 U.S.C. 102(b) as being anticipated by Chenal, (2002/0072670).

Re Claim 17: Chenal (2002/0072670) discloses, a system comprising:

A display configured to display an image of a heart and a representation of a probe, which is in or adjacent to the heart. Wherein the representation of the probe is registered with the image on the display using at least one feature of the heart. (See paragraph [0023]).

Re Claim 21: Chenal (2002/0072670) discloses, the system of claim 17, wherein the image comprises one or more images acquired using computed tomography, magnetic resonance or ultrasound. (See paragraph [0023]).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Willis (US 6,896,657).

Re Claim 1: Willis ('657) discloses, a method comprising:

- (a) Locating a feature of or relating to a heart with a probe which is inside a body; and
- (b) Registering a representation of the probe with an image of the feature of the heart.

(See col.2 line 45-50).

Re Claim 2: Willis ('657) discloses, the method of claim 1 further comprising repeating steps (a) and (b) for at least three features of or relating to the heart.

(See col.1 line 60- col. 2 line 10).

Re Claim 3: Willis ('657) discloses, the method of claim 1, wherein step (a) comprises contacting the probe with the feature. (See col.2 line 16-24).

Re Claim 4: Willis ('657) discloses, the method of claim1, wherein the feature is located on an interior of the heart. (See col. 1 line 60-68 and col.2 line 1-5).

Re Claim 5: Willis ('657) discloses, the method of claim 1, wherein the image is acquired using computed tomography, magnetic resonance, or ultrasound. (See col.17 line 19-27).

Re Claim 7: Willis ('657) discloses, a method comprising:

Acquiring at least three-dimensional image of an organ or structure inside a body;

Registering a representation of a probe, which is inside the body with the image using at least one feature of the organ or structure. (See background of invention and col.17 line19-35).

Re Claim 8: Willis ('657) discloses, the method of claim7, further comprising locating the at least one feature with the probe. (See col.1 line 60- through col. 2 line 5).

7. Claims 12 is rejected under 35 U.S.C. 102(e), as being anticipated by Rom (US 6,685,637).

Re Claim 12: Rom ('637) discloses, a system comprising:

A processor (30) configured to be communicatively coupled to a probe (10), the probe being configured to locate a feature pertaining to an organ or structure inside a body;

A memory (34) configured to store an image pertaining to the organ or structure inside the body, the image including the feature; and a display configured to simultaneously display (20) the image and a representation of the probe, the image being registered with the representation of the probe using the feature. (See Fig 1. also, col. 2 line 60-col. 3, line 25).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willis ('657) in view of Willis (US 6,490,474). The teachings of Willis ('657) have been discussed above.

Re Claim 6: However, Willis ('657) fails to disclose or fairly suggest the method, wherein the feature comprises a cardiac valve, cardiac appendage, or scar tissue.

Willis ('474) teaches selecting regions of cardiac tissue or desired locations within the heart. (See col.2, lines 15-29).

Therefore, in view of Willis ('474), it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a feature of the heart, such as the cardiac tissue, in order for physician to guide mapping the catheters.

10. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Willis ('657) in view of Sra (US 2005/0143777). The teachings of Willis ('657) have been discussed above.

Re Claim 9: However, Willis ('657) fails to disclose or fairly suggest the method of locating at least three features with the probe, and wherein the registering step comprises using the three features to register the representation of the probe with the image.

Sra (2005/0143777) teaches selected location is substantially devoid of features such as coronary vessels, nerves and scar tissue which would develop methods that would help to utilizing the registered 3D images to identify the location on the cardiac chamber. (See Paragraph [0021]).

Therefore, in view of Sra ('777), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have three-selected locations within the heart are required in order to develop steps to generate a 3D image of a feature of the heart was.

11. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willis ('657) in view of Nolte (US 2002/0120192). The teachings of Willis ('657) have been discussed above.

Re Claim 10: However, Willis ('657) fails to disclose or fairly suggest the method of one or more images acquired using computed tomography, magnetic resonance, or ultrasound.

Nolte (2002/0120192) teaches, the method of CT and MRI used to obtain 3D image of an organ as well as representation of the probe. (See [0006]).

Therefore, in view of Nolte ('192), it would have been obvious to one of ordinary skill in the art at the time the invention was made to use of MRI or CT images in order to determine the position of an organ and for position a therapeutic or diagnostic tool as a function of three-dimensional image.

Re Claim 11: However, Willis ('657) fails to disclose or fairly suggest the method of displaying the registered image, the registered representation of the probe, and a map of the electrical properties of the organ or structure inside the body.

Nolte (2002/0120192) teaches, the method of obtaining the registered image as well as the representation of the probe. (See paragraph [0006] and paragraph [0041]).

Therefore, in view of Nolte ('192), it would have been obvious to one of ordinary skill in the art at the time the invention was made to display the representation as well as the image in order to practitioner be able to modify equipment parameters such as the ultrasound frequency, gain, pulse power.

12. Claims 13, 14, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rom (US 6,685,637) in view of Chenal (US 2002/0072670). The teachings of Rom ('637) have been discussed above.

Re Claim 13: However, Rom ('637) fails to disclose or fairly suggest the method wherein the organ or structure (11) comprises a heart and the display (10) is configured to simultaneously display (10) a map of electrical properties (14) of the heart in conjunction with the image and the representation of the probe.

Chenal (2002/00726070) teaches, the discussion above on his invention. (See Fig.1; Paragraph [0023]).

Therefore, in view of Chenal ('670), it would have been obvious to one of ordinary skill in the art at the time the invention was made to examine the heart and to display the electrical properties of the heart in order to have a better analysis and display of ultrasonic diagnostic cardiac images.

Re Claim 14: However, Rom ('637) fails to disclose or fairly suggest the method wherein the image is at least a three-dimensional image (15a- 15c).

Chenal (2002/00726070) teaches, on that images of heart are taken in 3D (see Fig.1; Paragraph [0023]).

Therefore, in view of Chenal ('670), it would have been obvious to one of ordinary skill in the art at the time the invention was made to demonstrate the 3D images of the organ in order to have a better analysis and display of ultrasonic diagnostic cardiac images.

Re Claim 15: However, Rom ('637) fails to disclose or fairly suggest the method wherein the organ or structure comprises a heart (11).

Chenal (2002/00726070) teaches, the images taken from the apex of the heart is used for analysis of the heart electrical properties. (See Fig.1; Paragraph [0023]).

Therefore, in view of Chenal ('670), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the organ or structure as the heart in order to have a better analysis and display of ultrasonic diagnostic cardiac system.

Re Claim 16: However, Rom ('637) fails to disclose or fairly suggest the method of one or more images acquired using computed tomography, magnetic resonance, or ultrasound.

Chenal (2002/00726070) teaches, the ultrasound system being used to capture the image of the heart (see Fig.1; Paragraph [0023]).

Therefore, in view of Chenal ('670), it would have been obvious to one of ordinary skill in the art at the time the invention was made to take ultrasound images from the heart

which help practitioners in order to be able automatically delineate features which are clearly shown in an ultrasound image.

13. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenal (2002/0072670) in view of Osadchy (EP 1 086 649). The teachings of Chenal ('670) have been discussed above.

Re Claim 18: However, Chenal ('670) fails to disclose or fairly suggest the method of wherein the display configured to display a map of electrical properties of the heart in conjunction with the image and the representation of the probe.

Osadchy ('649) teaches, the display of cardiac cycle registered by using the catheter probe (See Abstract).

Therefore, in view of Osadchy ('649), it would have been obvious to one of ordinary skill in the art at the time the invention was made to display the electrical potential distribution of the heart chamber in order to examine the cardiac, will help the physicians to monitor the electrical properties of the different feature of the heart easily.

Re Claim 19: However, Chenal ('670) fails to disclose or fairly suggest the method of claim 19, wherein the display is configured to display electrical properties of the heart corresponding to at least one location of the probe in conjunction with the image and the representation of the probe.

Osadchy ('649) teaches, a method for intracardially surveying a condition such as an electrical property of a chamber of a heart with a catheter having a distal tip and a condition sensor contained therein. (See Abstract).

Therefore, in view of Osadchy ('649), it would have been obvious to one of ordinary skill in the art at the time the invention was made to display the electrical properties of the chamber of the heart using a catheter will allow the practitioner to monitor selected location within the heart, for more precise examine of the heart's electrical properties.

14. Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenal (2002/0072670) in view of Panescu (US 5,487,391). The teachings of Chenal ('670) have been discussed above.

Re Claim 20: However, Chenal ('670) fails to disclose or fairly suggest the method of wherein the image is at least a three dimensional image.

Panescu ('391) teaches, the system and methods for examining heart tissue and creating a three-dimensional output. (See Col.2 line 25-35).

Therefore, in view of Panescu ('391), it would have been obvious to one of ordinary skill in the art at the time the invention was made to display three-dimensional image as an

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output of examining of the heart will improve the methodologies to examine heart tissue morphology quickly, accurately and in a relatively on invasive manner.

Re Claim 22: However, Chenal ('670) fails to disclose or fairly suggest the method of claim 22, wherein the probe is configured to sense electrical properties of the heart.

Panescu ('391) teaches, the system and methods sense with the electrode the timing of a local depolarization event in the region of the heart tissue. (See col.1 line 60-70).

Therefore, in view of Panescu ('391), it would have been obvious to one of ordinary skill in the art at the time the invention was made to sense with the catheters the physiological properties of the heart e.g. depolarization in order to accurately and clearly monitoring the cardiac cycle.

15. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenal (2002/0072670) in view of Rom (US 6,685,637). The teachings of Chenal ('670) have been discussed above.

Re Claim 23: However, Chenal ('670) fails to disclose or fairly suggest the method of claim 23, wherein the system in configured to receive user input (50) in the form of commands identifying the feature in the image.

Rom ('637) teaches use of central controller by which the user control the ultrasound system for capturing or identifying the image.(See Fig. 1; col. 2 line 60-65)

Therefore, in view of Rom ('637), it would have been obvious to one of ordinary skill in the art at the time the invention was made to have human interface (e.g. keyboard) in order to control and performance of the ultrasound machines to receive more accurate and precise images.

Re Claim 24: However, Chenal ('670) fails to disclose or fairly suggest the method of claim 24, wherein the system is an electrophysiology monitoring system (20).

Rom ('637) teaches use of a display device for diagnostic images of ultrasound (See Fig. 1; col. 2 line 50-60)

Therefore, in view of Rom ('637), it would have been obvious to one of ordinary skill in the art at the time the invention was made to diagnose with video processor (18) which produces raster scan signals allows to display a diagnostic image, an further to monitor the electrical properties of the organs or structure inside the body captured by ultrasound, MRI or CT images.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicants disclosure. Ohno et al. discloses Beam scanning probe system for surgery, Ben Haim,

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discloses Apparatus and method for treating cardiac, Kimchy et al. discloses Radioactive emission detector equipped with a position tracking system and utilization thereof with medical systems and in medical procedures, Crowley, Robert discloses Medical imaging device, Porath et al. discloses Transient event mapping in the heart, Ameling et al discloses System for determining the intracorporal position of a working catheter.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to I. Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on 7:30 am to 4 pm Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jong-Suk (James) Lee can be reached on 571-270-1341. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IKK

I. Kenneth Kholdebarin
September 29, 2006

A handwritten signature in black ink, appearing to read 'J. Lee', with a large, stylized initial 'J'.

JONG SUK LEE
SUPERVISORY PATENT EXAMINER